REMARKS

This Amendment incorporates the features of claim 20 into claim 18. Claims 18, 19 and 21-30 are pending.

This Amendment overcomes the 35 U.S.C. 102(e) rejection of claims 18-30 over U.S. published application No. 2004/0229349 to Daridon. The claimed assay includes retaining biological particles containing an analyte(s) of interest on a filter, followed by removing the biological particles from the filter by a flush flow in a second direction opposite said first direction, and then analyzing biological particles contained in the flush flow by means of a nucleic acid amplification assay. The flush flow is analyzed for the analyte(s) without any purification.

Daridon fails to disclose or suggest the step of analyzing biological particles contained in the flush flow using a nucleic acid amplification assay without any purification. In this regard, Daridon mentions PCR only a few times: paragraph [0005] (Background of the Invention), paragraph [0246] (Detection sites), paragraph [0288] (Genotypic Assays) and paragraph [0308] (Single Cell Assays). None of these references to PCR disclose or suggest nucleic acid amplification analysis of an analyte without any purification. For example, paragraph [0246] discloses external

detection sites may be used to further manipulate and/or detect particles or particle components, and that these further manipulations and/or detection methods may overlap with, but preferably complement the manipulations/detections performed in the microfluidic system, including PCR among others. This brief mention of PCR fails to disclose or suggest a nucleic acid amplification assay without purification of the flush component.

Similarly, paragraph [0288] discloses that genotypic assays may be conducted using microfluidic systems to measure the genetic constitution of cells, and mentions that methods for genotypic assays may include polymerase-mediated amplification of nucleic acids by thermal cycling (PCR) or by isothermal strand-displacement methods. Again, this brief mention of PCR fails to disclose or suggest a nucleic acid amplification analysis without purification of the flush component.

Finally, paragraph [0308] discloses that microfluidic systems may be used to perform single-cell assays, with single cell PCR one of several examples listed. Again, this brief mention of PCR in the context of single-cell assays fails to disclose or suggest a nucleic acid amplification analysis should be performed without purification of the flush component.

The Patent Office reliance on paragraph [0449] to show analysis of a flush component without purification is misplaced. Instead, this paragraph merely discloses directing the flush flow to a separate analysis site. No mention is made, one way or the other, regarding purification of the flush flow. In this regard, the immediately preceding paragraph [0448] notes that an analysis site may be used to manipulate the contents of individual chambers, which clearly implies the flush flow will be subject to subsequent manipulation rather than an analysis without any purification.

One of ordinary skill in the art would not interpret paragraph [0449] as disclosing or suggesting nucleic acid amplification analysis should be performed without purification of the flush component, particularly given the total absence of such a disclosure in the paragraphs which discuss nucleic acid amplification assays. In short, claim 18 defines patentable subject matter over Daridon.

Claim 19 depends from claim 18, and further specifies performing an initial filtration step which does not retain the biological particles of interest, but instead retains particles which might interfere with the nucleic acid amplification analysis.

Daridon also fails to disclose or suggest the initial filtration step of claim 19. Paragraph [0538], cited by the Patent Office, merely discloses that a pump is used, among other purposes, to move cells away from filtering mechanism 1276 (Fig. 47) to reduce or prevent filter clogging. The prevention or reduction of filter clogging does not disclose or suggest the initial filtration step of claim 19.

Paragraphs [0858] and [0859] teach a form of particle pre-filtration which is directly opposite of claim 19. Instead of initially filtering/retaining possibly interfering smaller particles, Daridon teaches retaining larger particles of interest in its filtration mechanism 1656, while permitting the smaller particles to pass through.

Reconsideration and withdrawal of the anticipation rejection of claims 18-30 over Daridon are requested.

It is believed the application is in condition for allowance. Reconsideration and withdrawal of the rejection of claims 18-30, and issuance of a Notice of Allowance directed to claims 18, 19 and 21-30, are respectfully requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance of this application.

The extension fee is being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

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Enclosure:
Petition for Extension of Time